



# QUIP ADULT CARDIAC DATABASE (ACD)

## FOUNDING CHARTER

### 1. INTRODUCTION

- 1.1. This Charter is an agreement between the European Association for Cardio-Thoracic Surgery ("EACTS") and the various Cardio- Thoracic Surgery Centres [and National Societies and National Registries of Cardio-Thoracic Surgeons] listed in Appendix 1 as amended from time to time ("the Participants"). This Charter outlines the purpose, the principles and the rules governing the QUIP Adult Cardiac Database.
- 1.2. Any national society of cardiothoracic surgeons, or cardiothoracic surgery centre by submitting the registration form becomes a party to this Charter and agrees to comply with these rules.

### 2. DEFINITIONS

- 2.1. In this Charter the terms set out below shall have the following meaning:
  - 2.1.1. "ACD" shall mean the EACTS QUIP Adult Cardiac Database.
  - 2.1.2. "ACD Data" shall mean the aggregated and anonymised pre-/peri- and post-operative data of cardiothoracic surgery procedures submitted by the Participants (in the form of Extracts) and collectively held in the ACD.
  - 2.1.3. "Core Source Data" shall mean all pre-/peri and post-operative data relating to a cardiothoracic procedure, including data relating to the associated patient and surgeon data.
  - 2.1.4. "EACTS" shall mean the European Association for Cardio-Thoracic Surgery, a company limited by guarantee and incorporated in England and Wales under company number 07401765.
  - 2.1.5. "EACTS ACD Task Force" shall mean the sub-committee of EACTS members with responsibility for overseeing the management of the ACD.
  - 2.1.6. "The Quality Improvement Programme (QUIP) Committee" shall mean a committee of EACTS with responsibility for the oversight of all databases deployed by EACTS.
  - 2.1.7. "EACTS Council" shall mean a leadership body within EACTS that provides governance, direction and management of EACTS.
  - 2.1.8. "Extract" shall mean an anonymised extract of the Core Source Data, with all Identifying Markers relating to Relevant Individuals removed, submitted by a Participant for inclusion in the ACD.
  - 2.1.9. "GDPR" shall mean the UK General Data Protection Regulation and the EU General Data Protection Regulation (and any successor legislation).
  - 2.1.10. "Identifying Markers" means any data fields or information in the Core Source

Data which enable a Relevant Individual to be identified, either on its own when cross referenced with other information available or capable of being obtained by the recipient of such data. The information required to be removed in accordance with the protocols set out in [Appendix 4](#) of this Charter shall be deemed to be Identifying Markers and must be excluded from Extracts.

- 2.1.11. "Lead Surgeon" shall be the senior cardiothoracic surgeon residing at a Surgery Centre named on the Registration Form.
- 2.1.12. "National Registry" shall mean a national medical centre registry which has registered to participate in the ACD on behalf of the Surgery Centres in its remit.
- 2.1.13. "National Society" shall mean a national medical society which has registered to participate in the ACD on behalf of the Surgery Centres in its remit.
- 2.1.14. "Participant" shall mean one of the Surgery Centres or National Societies or National Registries listed in Appendix 1 (as amended from time to time) and any additional National Society, Registry or Surgery Centre whose registration to the ACD has been accepted by EACTS.
- 2.1.15. "Personal Data" shall have the meaning given to it in GDPR.
- 2.1.16. "Relevant Individuals" shall mean patients, medical practitioners or other individuals involved in an operation whose information is included in the Core Source Data relating to an operation.
- 2.1.17. "Registration Form" shall mean the application to participate in the ACD to be completed by each Surgery Centre or National Society or National Registry.
- 2.1.18. "Surgery Centre" shall mean a hospital (private or public) or other cardiothoracic surgery centre who has registered to participate in the ACD including those whose participation is via a National Society or National Registry.

### 3. OVERVIEW of the ACD

- 3.1. The ACD has been established to collect and store the ACD Data and fulfil the aims of the ACD as set out in clause 4 below.
- 3.2. Extracts of completed procedures are supplied by the Participants to EACTS for inclusion in the ACD.
- 3.3. The ACD aggregates the Extracts, to enable the aims of the ACD to be met.

### 4. AIMS of the ACD:

- 4.1. To allow Participants and EACTS members to examine the outcomes of cardiothoracic surgical procedures carried out in participating Surgery Centres and countries.
- 4.2. To enable Participants and EACTS members to compare their case mix and outcomes with the anonymised collective data shared by Participants (inter)nationally and identify quality improvement potential with online dashboard tools.
- 4.3. To facilitate detailed risk stratification of specific categories of patients which will enable medical professionals to advise patients and patient groups with more confidence about the risks involved in various procedures for patients sharing their

characteristics and medical history.

- 4.4. To facilitate scientific research for quality purposes.

## 5. AIMS of the EACTS ACD Task Force

- 5.1. To review the performance of the ACD, organise a regular review of the data fields within the ACD and report such outcomes and recommendations to the QUIP Committee.
- 5.2. To promote scientific research for quality improvement using the ACD Data.
- 5.3. To review and approve scientific research requests as described in the data request protocol (in conjunction with the QUIP Committee, EACTS Council or any EACTS specialist scientific council that may be established).
- 5.4. To review access to the ACD and to consider any requests for access other than as detailed in Clause 7 below.

## 6. DATA USAGE, DATABASE RIGHTS, DATA PRIVACY and GDPR COMPLIANCE

- 6.1. Participants are invited to submit anonymised details of cardiothoracic procedures which have been completed within their Surgery Centre or, in the case of National Societies and National Registries, within Surgery Centres within their remit.
- 6.2. Participants shall ensure that, before submitting Extracts to EACTS:
  - 6.2.1. Identifying Markers have been removed from the underlying Core Source Data in accordance with the protocols in [Appendix 4](#) (as updated from time to time); and
  - 6.2.2. such Extracts must be compliant with the standards detailed in Clause 9.
- 6.3. National Societies and National Registries shall require the Surgery Centres within their remit to prepare the Extracts in accordance with this Charter before sharing them with the relevant National Society or National Registry.
- 6.4. EACTS may update the protocols listed in [Appendix 4](#) from time to time and shall notify all participants if it does so.
- 6.5. EACTS shall be permitted to retain the Extracts in the ACD indefinitely on an irrevocable basis and be entitled to incorporate them into the ACD Data and use the data for the purposes set out in this Charter.
- 6.6. Participants shall be entitled to discontinue submitting Extracts to the ACD at any time. Any Extracts already submitted and accepted for inclusion in the ACD shall remain within the ACD Data.
- 6.7. All database rights arising in the pooled collective data that constitutes the ACD Data shall vest in, and remain the exclusive property of EACTS. Participants shall be permitted to access and use the ACD Data in accordance with clause 7.
- 6.8. It is the intention of EACTS and the Participants that the ACD Data is outside the scope of GDPR as Extracts are required to be submitted to EACTS in an anonymised

form.

- 6.8.1. In some exceptional circumstances it may be possible to identify an individual patient or surgeon from the Extract or indirectly from the surrounding data, with the result that the relevant Extract contains Personal Data.
- 6.8.2. To the extent that an Extract contains any Personal Data, it is acknowledged that EACTS will become an independent data controller of such Personal Data. EACTS maintains registration as a data controller with the Information Commissioners Office (application Z5303624).
- 6.8.3. EACTS obtains, stores and uses the ACD Data in accordance with the EACTS Data Privacy Notice in [Appendix 2](#).
- 6.9. If required by law, the contents of the ACD may be disclosed to regulatory or law enforcement bodies acting under appropriate legislation.
- 6.10. Participants' personal data, such as the name and contact details of the Participants, will be processed by EACTS for the purposes of managing access to the ACD and other EACTS services. Participants' personal data will not be stored within the ACD.

## 7. ACCESS

- 7.1. All EACTS members and authorised Participants are entitled to see and review the Data presented via the ACD Dashboard. These users will be able to review the ACD Data presented on an individual Surgery Centre level, but the Surgery Centre names will be anonymised; it will not be possible to identify a Surgery Centre.
- 7.2. The Lead Surgeon of each Participant will also be able to nominate a limited number of users who are able to identify the data of their own specific Surgery Centre and in dashboards the position of their named Surgery Centre in comparison to the anonymised other Participants.
- 7.3. EACTS may from time to time receive research requests. Where such a request is approved by the ACD Task Force and EACTS, an EACTS Data Analyst will provide a suitable extraction of the ACD Data which covers the needs to answer the research question. No researcher will be provided with direct access to the ACD.
  - 7.3.1. Where EACTS approves a research request, the ACD Data will be made available to the researcher under defined conditions, with usage of the relevant data or report restricted to the research for which it was requested. Researchers will only be permitted access to data where individual Surgery Centre name(s) are anonymised.
- 7.4. EACTS may also provide extracted reports to Participants, containing their own Extracts, on request. For example, a National Society may request data based on the Surgery Centres from their country whose Extracts they have provided, or in comparison to other national bodies.
- 7.5. Whilst the ACD has been created and developed for non-commercial purposes, EACTS shall be empowered to make charges to researchers and others to whom access is granted.

- 7.6. EACTS may also, at its discretion, perform its own analysis on the ACD and produce reports. Non-hospital-identifiable reports of a more general nature may be used by EACTS for the purposes of press reporting, use in scientific publications or similar, lobbying, advertising or similar, and may be posted on the EACTS website for public access. Analysis and reports requested by third parties will also follow the data request protocol.
- 7.7. Publications to scientific journals will be reviewed and agreed on beforehand by EACTS. Current standards for co-authorship will be observed and all Participants' centres of the study will be acknowledged.

## 8. PARTICIPANT REGISTRATION

- 8.1. Any National Society, National Registry or Surgery Centre wishing to participate in the ACD must initially complete the ACD Registration Form. They will become a Participant when their registration is accepted by EACTS.
  - 8.1.1. An ACD Registration Form submitted by a National Society or a National Registry must list the relevant Surgery Centres within the jurisdiction of that National Society
- 8.2. The Participants are responsible for:
  - 8.2.1. Providing information with respect to the methods of data validation;
  - 8.2.2. Providing accurate, complete and robust Extracts;
  - 8.2.3. Ensuring that participation in the ACD complies with any applicable local laws and internal procedures; and
  - 8.2.4. Advising EACTS of any change in circumstances affecting its participation; or the reliability and completeness of the Extracts that it is supplying.
- 8.3. Where a National Society or a National Registry submits data to EACTS on behalf of Surgery Centres within the jurisdiction of the National Society, either:
  - 8.3.1. each individual Surgery Centre must have individually subscribed to this Charter; or
  - 8.3.2. the National Society must warrant that it is authorised by each individual Surgery Centre to submit data on behalf of that Surgery Centre and be able to provide evidence of that authorisation where required to do so by EACTS.
- 8.4. EACTS reserves the right to refuse registration of the Participant and may terminate participation at any time or make continued participation conditional upon such terms as it may impose.

## 9. DATA VALIDATION

- 9.1. The reliability of the submitted data is a vital element of the operation of the ACD.
- 9.2. Extracts may be submitted to EACTS for inclusion into the ACD by the registered Participants only.
  - 9.2.1. Participants are responsible for ensuring that only properly authorised persons submit Extracts to the ACD.

- 9.3. Extracts must be submitted using the fields and definitions supplied by EACTS.
- 9.4. Participants undertake to ensure that each Extract submitted is accurate, complete and robust. Each Participant undertakes to:
  - 9.4.1. Ensure that patient and surgeon personal data is anonymised prior to submission to EACTS;
  - 9.4.2. Crosscheck data against other local sources of data, such as operative logs or administrative data to ensure that case ascertainment is complete;
  - 9.4.3. Utilise local independent sources of mortality to ensure that mortality returns are accurate; and
  - 9.4.4. Monitor data accuracy to ensure that risk factors are reliably recorded.
- 9.5. EACTS is not obliged to verify whether each Extract fulfils these requirements, however, it will:
  - 9.5.1. Validate Extract submissions for completeness and alignment of fields and definitions to EACTS' requirements; and
  - 9.5.2. Utilise any audit procedures already organized by National Societies/Registries where possible and to further utilise such steps as it considers reasonably necessary to audit the Extract submitted by any Participant.
- 9.6. EACTS reserves the right to remove data from the ACD or take such other steps as may seem appropriate if it suspects that data is not robust or for any other reason and without being required to give any explanation.
- 9.7. EACTS shall not be responsible for any inaccuracies in the ACD and shall be indemnified by Participants in respect of any harm caused to any person in any way as a result of inaccurate data being supplied; or information being supplied without the required consent.

## 10. LEGAL AND SUPERVISING AUTHORITIES

- 10.1. This Charter is subject to the laws of England and Wales and shall be subject to the exclusive jurisdiction of the courts of England and Wales.
- 10.2. The EACTS Council is EACTS' official body responsible for strategic decisions regarding the ACD.
- 10.3. In the first instance, any disputes arising from, or in connection with this Charter or the use or application of the ACD shall be referred to the EACTS Council. The parties will then work together in good faith to resolve the dispute amicably.

## 11. DOCUMENT CONTROL

- 11.1. This document is controlled by EACTS at the version level stated in the footer to this document.
- 11.2. Any amendments to this document will be governed by EACTS and subject to internal EACTS approval.

- 11.3. Surgery Centres or National Societies will be notified and informed periodically of any changes to this agreement. Following notification of any such changes, any Surgery Centre or National Society may revoke their Participant Registration and cease to be a Participant in the ACD. In such circumstances, clause 6.4 shall continue to apply.

# APPENDIX 1

## CARDIO-THORACIC SURGERY CENTRES AND SURGEONS

Appendix 1 is a separate document which is a list of Participants, to be completed by EACTS and stored securely at EACTS House, Windsor, UK.

Any Cardio-Thoracic Surgery Centre, National Society, or surgeon by submitting the registration form becomes a party as a Participant to this Charter and will be added to Appendix 1.

# APPENDIX 2

## EACTS DATA PRIVACY NOTICE

The European Association for Cardio-Thoracic Surgery Privacy Notice for the Adult Cardiac Database (ACD).

### Our contact details

Name: European Association for Cardio-Thoracic Surgery

Address: EACTS House, Madeira Walk, Windsor, SL4 1EU, United Kingdom

Phone Number: +44 (0) 203 959 3110

E-mail: [info@eacts.co.uk](mailto:info@eacts.co.uk)

### What type of information we have

- We currently collect and process the following information:
- We collect anonymised patient information relating to the treatment of cardiothoracic medical conditions, the pre-existing medical conditions of the patient, and the patient's follow-up care and recovery.
- We do not collect any personal information relating to individual patients or the surgeon who carried out any medical intervention.

### How we get the information and why we have it

Anonymised patient information is provided to us directly from one of the following sources:

- Surgery Centres who subscribe to the EACTS database.
- National Societies and National Registries who support the EACTS aims and who submit the information on behalf of the Surgery Centres they represent.

We hold this information to enable EACTS to complete statistical analysis on cardiothoracic intervention treatments, and to provide that analysis to its members, to organisations who contribute data and the wider academic health community. This statistical analysis aims to identify cardiothoracic treatments that provide improved recovery outcomes for patients. It can be used to identify the most beneficial intervention to take, given a patient's current and historic medical conditions, through comparison with other previous patients worldwide with a similar medical history.

It can be used by hospitals to understand their safety, efficiency, and efficacy in the treatment of cardiothoracic conditions, relative to other hospitals.

The aim of the database is to foster the adoption of good practice, improve quality, and to monitor the efficacy of new or emergent treatment regimes, and thereby improve patient outcomes.

### Lawful Basis

EACTS receives anonymised information only from supplying organisations. It is not possible to identify individuals from the data held alone, or without reference to further data that is not held within EACTS.

However, there may be exceptional circumstances where identification is possible due to the unique medical data relating to a specific patient, or where a patient's medical treatment details become publicly known.

Under such exceptional circumstances, EACTS relies on the following grounds as its lawful basis under Article 6 and Article 9 of the General Data Protection Regulations (GDPR) for processing this information:

- Article 6: We have a legitimate interest in processing the data we collect for the purposes set out in this privacy policy. EACTS has completed a Legitimate Interests Assessment
- Article 9: In accordance with Article 9.2 (i) of the GDPR and paragraph 3 of Part 1 of the Data Protection Act 2018, our processing is necessary for reasons of public interest in the area of public health, by ensuring high standards of quality and safety of health care and of medicinal products or medical devices.

### What we do with the information we have

We use the information that Surgery Centres and National Societies and National Registries have given us in order to populate one or more databases that is managed by EACTS.

The database(s) provide statistical and analytical output for comparative purposes.

We may share this information with Surgery Centres, National Societies, National Registries, individual subscribing Members of EACTS, researchers or other users with legitimate interest.

### How we store your information

The information provided by Surgery Centres, National Registries and National Societies is securely stored within EACTS cloud databases. The ACD is hosted on a Microsoft Azure Cloud Data Centre hosted in within the EU.

We keep all data provided to us by Surgery Centres, National Registries and National Societies. We do not routinely delete data, as the historical trend and comparison data is an integral element of the statistical and analytical output of our database.

### Your data protection rights

EACTS has no access to personal information. The information held within EACTS is anonymised, and so individual personal data cannot be identified for the purpose of providing copies of personal information, rectification, erasure, or any other data protection rights.

If an individual wishes their anonymised data not to be included in a submission from a Surgery Centre or a National Society, then the individual needs to contact the Surgery Centre or National Society direct and request its removal from the Surgery Centre records.

If an individual's anonymised data has been redacted from a Surgery Centre or National Society records, then it will not form part of a future submission from that Surgery Centre or National Society to EACTS, and the individual's data will then no longer form part of the EACTS database.

#### How to complain

You can also complain to the ICO if you are unhappy with how we have used your data.

The ICO's address:

Information Commissioner's Office

Wycliffe House

Water Lane

Wilmslow

Cheshire

SK9 5AF, United Kingdom

Helpline number: 0303 123 1113

# APPENDIX 3

## DATABASE TECHNICAL AND SECURITY REQUIREMENTS

The ACD has been developed on behalf of EACTS by a specialist IT application provider. The technical and security requirements listed in this Appendix 3 are those currently agreed between EACTS and the developer/supplier of the ACD application. EACTS will make all reasonable efforts to ensure compliance with these requirements, but reserves the right to amend, change and update the ACD, its specification or its functionality at any time.

The ACD will conform to the following technical and security specification:-

1. Availability, access and usage
  - 1.1. Authorised users will be able to log in to the ACD using a defined log in process utilising two-factor authentication (2FA)
  - 1.2. The ACD will be available to users 24 hours a day, every day of the year, other than downtime for maintenance or release upgrades
  - 1.3. The ACD will be compliant with standard office hardware and mobile technology. It will work with Windows 10 Desktop OS or newer, and the latest current version of iOS and Android and the major version -1. It will be compatible with Edge, Safari and Chrome browsers.
  - 1.4. The ACD will consider WCAG access requirements, to AA standard, and apply these where it is practical to do so
  - 1.5. The system shall be usable on all channels and using mouse and touchpad pointer devices
  - 1.6. The ACD will be performant in use regardless of the physical location of the user, subject to the local internet access speeds
  - 1.7. No user analytics or tracking that uses cookies will be deployed on the ACD
  - 1.8. EACTS shall monitor system performance analytics available through the Azure platform
2. Storage, Back-up and recovery
  - 2.1. The database will be hosted on Microsoft Azure platform based in the EU. The primary data storage will be in Western Europe. The backup will be hosted in a Microsoft Azure platform geographically dispersed elsewhere in the EU.
  - 2.2. The platform will offer availability of at least 98.5% SLA
  - 2.3. The platform will be hosted in an environment which provides industry standards of physical access security
  - 2.4. The data within the database will be backed-up at least every 24 hours
3. Change and Release
  - 3.1. Vulnerability and Security patches will be deployed proactively

- 3.2. All revisions to the system will be tested prior to be release
- 3.3. Changes will not be tested in the live environment
- 3.4. Any release will be capable of being rolled-back and such roll-back will also be tested prior to deployment of any new release into the live environment
- 4. Compliance
  - 4.1. The system shall not compromise the integrity of the data in the underlying database
  - 4.2. The system shall comply with data protection regulations throughout Europe and the terms of the General Data Protection Regulations (GDPR) applicable to Europe and the UK
  - 4.3. The system shall operate in compliance with any Intellectual Property Rights established by owners of any underlying source code
- 5. Security
  - 5.1. Users will need to access the system using two-factor authentication (2FA)
  - 5.2. The system will deploy industry Security Best Practice, including implementation of a Web Application Firewall and Intrusion Detection System. These will be integrated with Microsoft Azure Security Monitor
  - 5.3. All data will be encrypted at rest and in transit
  - 5.4. All users will be validated by reference to Azure AD
  - 5.5. Encryption technologies will be used to secure sensitive user traffic
  - 5.6. A process will be implemented for adding new Participant data to the database. This will be an offline function managed by EACTS, and will not impact the usability of the ACD during this process
  - 5.7. Developers and third line support will have no direct access to the Production Environment

# APPENDIX 4

## IDENTIFYING MARKERS

Surgery Centres shall implement the protocols set out in this Appendix 4 to remove Identifying Markers from Core Source Data prior to submission to EACTS for inclusion in the ACD.

National Societies or National Registries that submit Extracts obtained from Surgery Centres within their remit shall ensure that those Surgery Centres implement the protocols set out in this Appendix 4 prior to submission to EACTS for inclusion in the ACD.

### Protocols to remove Identifying Markers:

- Names of Relevant Individuals shall be removed.
- Addresses, telephone numbers, email addresses and other contact details of Relevant Individuals shall be removed. A field for approximate geographic area of a patient's record may be included for epidemiological purposes – such as a county, region and/or the country. The name and address of the Surgery Centre conducting the procedure may also be included with the Extract – this will be handled in accordance with clause 7 of the Charter.
- The dates of birth of Relevant Individuals shall be removed. An age in years shall be specified instead.
- Any other data that is likely to result in a Relevant Individual being capable of being re-identified after submission shall also be removed.